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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,508	12/05/2003	Lavinia C. Popescu	02.36US	9085
23487	7590	02/22/2005	EXAMINER	
THE ESTEE LAUDER COS, INC 125 PINELAWN ROAD MELVILLE, NY 11747			KOSSON, ROSANNE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/728,508

Applicant(s)

POPESCU ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-4, 6-13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (U.S. 5,490,980) in view of Green et al. (US 5,525,336); Kanebo Ltd. (JP 02-204407, see English abstract); Dane, Hair Chemistry 1, The Trichological Society, [www.hairscientists.org/hair-chemistry.htm](http://www.hairscientists.org/hair-chemistry.htm), ©2000, printed from the Internet on July 26, 2004, and the record for transglutaminase from BRENDA, [http://www.brenda.uni-koeln.de/php/result\\_flat.php4?ecno=2.3.2.13](http://www.brenda.uni-koeln.de/php/result_flat.php4?ecno=2.3.2.13), printed July 26, 2004. As discussed in the previous Office Action, Richardson discloses a method of cross-linking human keratin proteins, including those found in hair, by applying a composition comprising an effective amount of transglutaminase to hair. Richardson also discloses a method of covalently bonding an alkyl amine moiety, such as in lysine, to a glutamine residue, both of which are contained in the keratin of hair, by contacting the hair with a composition comprising an effective amount of transglutaminase (see column 1, lines 14-20; column 1, line 51, to column 2, line 8; column 2, lines 23-38). The source of the transglutaminase may be mammalian or microbial and may be present in an amount of 0.001% to 20% (see column 10, line 53, to column 11, line 8). Transglutaminase cross-links keratin by the acyl transfer reaction of a glutamine residue (acyl acceptor) and a lysine residue (amine donor). This reaction can occur

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intramolecularly or intermolecularly (see the BRENDA reference, p. 5, which references prior works on transglutaminase from 1985 onwards). One of ordinary skill in the art would have been motivated to combine the teachings of Richardson and BRENDA to produce a composition for cross-linking hair to maintain curl, because BRENDA teaches that protein molecules such as keratin in hair, which contain glutamine and lysine residues, may be cross-linked by transglutaminase alone (without an additional alkylamine compound), and the skilled artisan would have recognized that the composition of Richardson, with or without the alkylamine compound, would have been used to cross-link hair. Additionally, as hair possesses a certain degree of curl, the application of transglutaminase to hair, described by Richardson, because of the cross-linking reaction, results in retention, enhancing and imparting of curl to hair.

Further regarding the action of transglutaminase on hair, Green discloses a composition comprising transglutaminase that is applied to hair. Transglutaminase is a cross-linking agent that cross-links corneocyte proteins that are present in the stratum corneum of the skin, hair or nails, thereby resulting in formation of a cross-linked layer (see col. 2, lines 25-36; and col. 3, lines 37-47). Cross-linking occurs in the presence of calcium ions, which are naturally present in all bodily tissues. Kanebo also discloses a hair cosmetic composition comprising transglutaminase. Transglutaminase catalyzes the cross-linking reaction of free glutamine residues with lysine residues in the outermost layer of the hair. This treatment imparts, i.e., greater density and springiness to the hair (see English abstract). One of ordinary skill in the art would have been motivated to combine the teachings of Richardson with the teachings of Green or

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Kanebo to produce a composition for cross-linking hair to maintain curl, because Green teaches that transglutaminase alone may be applied to hair and that it cross-links hair. Kanebo also teaches that transglutaminase alone may be applied to hair and that it forms links between glutamine and lysine residues in the outer layer of hair.

Richardson does not disclose the pH of the composition or applying heat to hair after applying the transglutaminase composition.

Dane discloses, as is well known in the art of perming hair, that in creating curls and waves, disulfide bonds between the amino acids of keratin in hair are broken and new ones formed, thereby cross-linking the keratin in a new arrangement (see last paragraph). Thus, one of ordinary skill in the art at the time that the invention was made would have recognized that in designing a product to maintain or enhance the curl of permed hair, it would have been advantageous to have included an ingredient that can cross-link keratin, as disclosed by Richardson, Green, Kanebo or BRENDA, to maintain the new cross-linking pattern in hair resulting from the perm by applying a second cross-linking agent. The skilled artisan would have been motivated to use the method of Richardson to maintain or enhance the curl of permed hair, because Richardson teaches that applying a transglutaminase composition can not only cross-link hair, it can also condition and repair damaged hair by catalyzing the reaction of primary amines with superficial glutamines in hair keratin (see column 18, line 44, to column 19, line 27).

Regarding the pH of the transglutaminase composition, it is well known in the art that human transglutaminase has a pH optimum of 6 (see record for transglutaminase from the BRENDA database, top of p. 19). Thus, it would have been obvious to one of

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ordinary skill in the art that, in preparing a composition comprising transglutaminase, as disclosed by Richardson, an appropriate pH would have been approximately 6.

With respect to applying heat to a keratinous material after applying a transglutaminase-containing composition, it is well known in the pertinent art that, after conditioning or applying a therapeutic treatment composition to hair, the hair may be subjected to heat with a hair dryer or blow dryer to style or reinforce curls. Thus, it would have been obvious to one of ordinary skill in the art that, following the treatment of hair with a composition comprising an effective amount of transglutaminase to maintain or enhance curl, as disclosed by Richardson, the hair would have been subjected to heat to style the curled hair or to reinforce the curl. Thus, a holding of obviousness is required.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (U.S. 5,490,980) in view of Green et al. (US 5,525,336); Kanebo Ltd. (JP 02-204407, see English abstract); Dane, Hair Chemistry 1, The Trichological Society, [www.hairscientists.org/hair-chemistry.htm](http://www.hairscientists.org/hair-chemistry.htm), ©2000, printed from the Internet on July 26, 2004, and the record for transglutaminase from BRENDA, [http://www.brenda.uni-koeln.de/php/result\\_flat.php4?ecno=2.3.2.13](http://www.brenda.uni-koeln.de/php/result_flat.php4?ecno=2.3.2.13), printed July 26, 2004; and further in view of product literature for eyelash perms from E-Z Permanent Makeup (<http://www.eyelashperm.com>, which has an embedded link for ordering and product information at <http://www.ezpermanentmakeup.com>), printed from the Internet

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on July 26, 2004. The rejection of claims 1-4, 6-13 and 15-18 over Richardson, Green, Kanebo, Dane and Brenda is discussed above.

E-Z Permanent Makeup discloses that a permanent wave may also be applied to eyelashes, another form of human keratin protein. Accordingly, one of ordinary skill in the art at the time that the invention was made would have recognized that in designing a product to maintain or enhance the curl of permed eyelashes, it would have been advantageous to have included an ingredient that can cross-link keratin, as disclosed by Richardson, Green, Kanebo and BRENDA to maintain the new cross-linking pattern in the eyelashes resulting from the perm by applying a second cross-linking agent. The skilled artisan would have been motivated to use the method of Richardson to maintain or enhance the curl of permed eyelashes, because Richardson teaches that applying a transglutaminase composition can not only cross-link keratin, it can also condition and repair damaged keratin by catalyzing the reaction of primary amines (which are present in keratin) with superficial glutamines in the keratin (see column 18, line 44, to column 19, line 27). Thus, a holding of obviousness is required.

All of Applicants' arguments have been considered but are not persuasive of error. Applicants assert that Richardson's intent is to bind an active component to the transglutaminase before applying the transglutaminase to hair. Because the glutamine residues will be occupied by the "active," presumably the active component, they will not be available to be cross-linked to the lysine residues in keratin. Applicants also assert that Richardson suggests that transglutaminase can be used only to link an exogenous

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amine-containing conditioning agent to hair and does not disclose that transglutaminase itself can condition hair. Further, Applicants assert that BRENDA does not disclose curl-inducing or –retaining properties and that BRENDA is not prior art.

In reply, as discussed above, Richardson discloses that transglutaminase is an enzyme responsible for cross-linking proteins by the formation of covalent bonds between lysine and glutamine residues (see col. 1, lines 14-18). Richardson also cites Japanese patent application no. 03-213574, which discloses the use of transglutaminase to cross-link the amino acid functional groups of the cuticle part of animal hair to produce hair having good shrinkage resistance, pill resistance and hydrophobic property (sic) (see col. 1, lines 51-55). Although Richardson discloses compositions comprising transglutaminase and an alkylamine compound, the reference does not disclose anywhere that the alkylamine compound is bound to the enzyme. Thus, when applied to hair, a composition of Richardson contains an enzyme that acts on multiple substrates. The transglutaminase cross-links the alkylamine compound to hair, and the transglutaminase cross-links hair by reacting glutamine and lysine residues. Regarding conditioning hair, Richardson discloses that the process involves the covalent attachment of primary amines to exposed glutamines at the hair fiber surface. Potential benefits include permanent conditioning or damage repair where the functional group is an alkyl chain/silicone or protein respectively (see col. 18, line 65, to col. 19, line 3). Thus, when lysine is the functional group, conditioning and damage repair (certainly at least damage repair, which substantially improves the appearance of hair, particularly permed hair, to make it appear conditioned), would have been



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expected. Regarding BRENDA, the reference was cited to provide additional information on the glutamine-lysine reaction catalyzed by transglutaminase and to point out literature in which this reaction is described. BRENDA cites publications on human transglutaminase that date back to 1985. Although BRENDA was not printed before Applicants' filing date, it demonstrates that the glutamine-lysine reaction catalyzed by transglutaminase was known long before Applicants' filing date. BRENDA was not cited for information on curl retention or induction.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

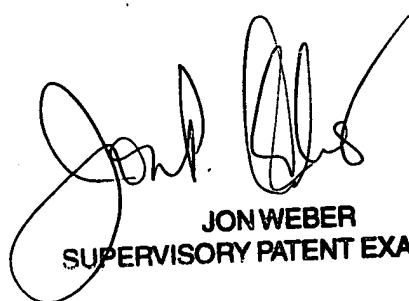
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
Art Unit 1651

rk  
2005-02-11



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**